NOTICE - SOME ITEMS SUPERSEDED OR OBSOLETE

Schedule Number: N1-088-04-003

Some items in this schedule are either obsolete or have been superseded by new NARA approved records schedules. This information is accurate as of:08/22/2022

ACTIVE ITEMS

These items, unless subsequently superseded, may be used by the agency to disposition records. It is the responsibility of the user to verify the items are still active.

All items except those listed below are active

SUPERSEDED AND OBSOLETE ITEMS

The remaining items on this schedule may no longer be used to disposition records. They are superseded, obsolete, filing instructions, non-records, or were lined off and not approved at the time of scheduling. References to more recent schedules are provided as a courtesy. Some items listed here may have been previously annotated on the schedule itself.

Item 5.1 is superseded by GRS 1.2, Item 020 (DAA-GRS-2013-0008-0001)

Item 5.2 is superseded by GRS 1.2, Item 021 (DAA-GRS-2013-0008-0006)

To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION 8601 ADELPHI ROAD COLLEGE PARK, MD 20740-600 1. FROM (Agency or establishment) Department of Health and Human Services 2. MAJOR SUBDIVISION Food and Drug Administration 3. MINOR SUBDIVISION 4. NAME OF PERSON WITH WHOM TO CONFER Seung Ja Sinatra 6. AGENCY CERTIFICATION I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal of the attatered — page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO manual for Guidance of Federal Agencies, is not required; is attached; or has been requested. SIGNATURE OF AGENCY REPRESENTATIVE A. P. Barnes A. P. Barnes MARCHIVIST OF THE UNITED STATES STATE	REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUME	BER NI - 9	88-04-03	
Department of Health and Human Services 2. MAJOR SUBDIVISION Food and Drug Administration 3. MINOR SUBDIVISION 4. NAME OF PERSON WITH WHOM TO CONFER Seung Ja Sinatra 6. AGENCY CERTIFICATION I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal of the attacked page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO manual for Guidance of Federal Agencies, X is not required; is attached; or has been requested. A P. Barnes Manual Proposed Disposition 9. GRS OR SUPERSEDED 10. ACTION TAKEN						
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3303a, the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10. 4. NAME OF PERSON WITH WHOM TO CONFER Seung Ja Sinatra 5. TELEPHONE Seung Ja Sinatra 6. AGENCY CERTIFICATION I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal of the attacked page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO manual for Guidance of Federal Agencies, X is not required; is attached; or has been requested. A. P. Barnes HIS Records Officer 7. ITEM NO 8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION 9. GRS OR SUPERSEDED 10. ACTION TAKEN	Department of Health and Human Services			5		
amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10. 4. NAME OF PERSON WITH WHOM TO CONFER Seung Ja Sinatra 5. TELEPHONE 301-827-4274 6. AGENCY CERTIFICATION I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal of the attatered page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO manual for Guidance of Federal Agencies, X is not required; is attached; or has been requested. A. P. Barnes Manual Fraction	2. MAJOR SUBDIVISION		3303a, the disposition request, including			
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A. P. Barnes J.	that the records proposed for disposal of the attathed page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO manual for Guidance of Federal Agencies,					
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	A. P. Barnes					
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Unless specifically stated otherwise in the description or the retention, all items are media-neutral and apply to paper, electronic, microform, or other media in which records may exist.

See Attached Sheet

FDA Administrative Records

Seung Ja Smatra - FDA Records Officer

Date

Fred Ansell - FDA Office of the Chief Counsel

Date

115-109

PREVIOUS EDITION NOT USABLE

STANDARD FORM SF 115 (REV. 3-91) Prescribed by NARA 36 CFR 1228

NWML

Ce agency, DR, DWMD, DWMW, DWCTC

Administrative Program Records

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
1.	Administrative Directives (Staff Manual Guides (SMGs)).	
1.1	Organizations (Staff Manual Guides, Volume 1). Functional statements, organization charts, clearances and essential supporting documents relating to FDA organization.	Supersedes RCS Item 7 and A3-5
1.1.1	Approved Organizations.	921
a u g	PERMANENT: Cut off at end of calendar year in 5 year blocks when superseded. Transfer to FRC 10 years after cutoff. Transfer to NARA 20 years after cutoff.	+)
1.1.2	Unapproved or Withdrawn Organizations:	
	TEMPORARY: Cut off at end of calendar year in which it is	
	disapproved or withdrawn. Destroy 10 years after cutoff.	
1.2	Delegations of Authority (Staff Manual Guides, Volume 2).	30
1.2.1	Delegations of Authority (Programs). Delegations issued by the FDA Commissioner, Center Directors and other senior management that assign to others responsibility for mission-related programs and authorize them to take actions on their behalf.	Supersedes RCS Item 7 and A3-6
	PERMANENT: Cut off in 5 year blocks at end of calendar year in which it is superseded. When volume permits, retire to FRC. Transfer to NARA 20 years after cutoff.	
1.2.2	Administrative Delegations of Authority. Delegations issued by the FDA Commissioner, Center Directors and other senior management that assign to others responsibility for administrative programs and authorize them to take actions on their behalf.	
	TEMPORARY: Cut off when superseded. When volume permits retire to FRC. Destroy 20 years after cut off.	
1.2.3	Interim Delegations of Authority. Delegations issued to authorize the individuals to act on their supervisor's behalf during their absence or for a specific activity. These records are effective for a short period of time.	

TEMPORARY: Destroy when no longer needed.

Item No. **Records Description and Authorized Disposition** NARA Approved Citation 1.3 Administrative Responsibilities and Procedures Manuals (Staff Manual **Supersedes** Guides, Volume 3). **RCS Item 7** Records cover administrative operational procedures and instructions relating to the implementation of administrative functions and policies issued by FDA administrative program offices. **TEMPORARY:** Cut off when superseded or obsolete. Destroy 20 years after cutoff. **GRS 16, Item 1** 2. Administrative Issuances. 2.1 Notices and other types of issuances related to routine administrative functions (e.g., payroll, procurement, personnel). TEMPORARY: Destroy when superseded or obsolete. 2.2 Case files related to 2. Labove that document aspects of the development of the issuance. **TEMPORARY:** Destroy when issuance is destroyed. **New Item** 3.1 Office of Inspector General (OIG) Reports. Records consisting of FDA responses to reports conducted by the Office of the Inspector General and material regarding the implementation of OIG's recommendations. These files consist of working drafts, draft reports, public comments, and the final report from OIG, agency comments to OIG on the draft, and an implementation plan for the final report. **TEMPORARY:** Cut off when all the recommendations of the report have been implemented within the agency. Destroy 10 years after cutoff. OIG Administrative Reviews. 3.2 Documents the reviews conducted by FDA for the centers and district

offices regarding their administrative procedures (procurement, budget,

property management, etc). These records may include copies of reviewers' annotated checklists, copies of comments, a final summary

document/report, and background materials.

Item No. **Records Description and Authorized Disposition NARA Approved** AND INSPECTION Citation 3.2.1 Audit Case Files. Reviews of the district offices' administrative policies conducted by a team of FDA auditors. Records include a final report that includes copies of the annotated checklists, comments, and required tasks to be completed. **TEMPORARY:** Cut off when the final required task is completed. Destroy 8 years after cutoff. 3.2.2 Self Assessments. Records documenting each center's reviews of their administrative policies and procedures to provide a consistent basis for determining areas of improvement and where training needs to be focused. These files consist of annually submitted checklists and summaries of required tasks. **TEMPORARY:** Cut off when the final required task is completed. Destroy 8 years after cutoff. Interagency Agreements/Memoranda of Understanding, Agreement and No change 4. understandings with other agencies, both technical and administrative for NC1-88-78-1, work to be done, time frames, costs or other remuneration, and details of Item A5-1 the personnel and equipment involved. Also includes subsequent amendments, comments, approvals and related correspondence. 4.1 Final Agreement/ Understanding Documents. **TEMPORARY:** Destroy 2 years after termination of entire agreement/ understanding. 4.2 Background/Working Files. **TEMPORARY:** Destroy 2 years after termination of entire agreement/ understanding. 5 Grants. Supersedes Notice of grant awards, opinions, comments, approvals or declinations NC1-88-78-1, funding documents, progress and expenditure reports, published materials, Item A5-2 and correspondence concerning grants awarded by FDA. 5.1 Grants Awarded by FDA.

TEMPORARY: Cut off after termination of grant or date of final

payment, whichever is later. Destroy 7 years after cut off.

Item No. Records Description and Authorized Disposition

NARA Approved Citation

Grants Approved (but not funded) or Disapproved Applications.

TEMPORARY: Destroy year after cancel date or after competitive review date, whichever is applicable.

6. Acquisition Library Database. System tracks the information on closed grants and contracts such as work description, property, and personnel involved, period of performance, billing and payment information. The system functions as a finding aid for the office.

New Item

TEMPORARY: Destroy or delete with related procurement records.

7. Agency Information Management System (AIMS).

New Item

- AIMS, a database management system, provides application tracking, document management, and reporting capability for various modules, and functions as an access entry point. AIMS tables provide a common source of core data elements shared by two or more modules. Some of the modules supported by AIMS are Dockets System, Federal Register Documents Tracking System, Ethics, Freedom of Information Tracking System, Awards Program and others. Access is restricted at the module level. Some modules are protected under the Privacy act.
- 7.1 <u>Inputs.</u> Data elements are input into a table upon its creation and entered by authorized users designated for each module.

TEMPORARY: Destroy when no longer needed for input or verification purposes. If input data is part of a records series under a particular module, apply retention for that series.

Note: Personnel and organizational data directly fed into AIMS from EASE (Enterprise Administrative Support Environment) do not create input files.

7.2 <u>Data Files.</u> Includes the information updated by authorized users assigned to each module. Also includes personnel and organization data fed from EASE periodically. Data Files are linked to the records in the various modules.

TEMPORARY: Maintain data for the longest retention period required by the modules.

7.3 Outputs. See the outputs under the various modules. The system has no specific outputs itself.

Item No. Records Description and Authorized Disposition

NARA Approved Citation

GRS 24, Item 4

- 7.4 <u>System Documentation.</u> See the documentations for the various modules. The emphasis has been on documentation for the modules rather than the core elements.
- 7.5 System Backup. Backup tapes maintained for potential system restoration in the event of a system failure or other unintentional loss of data.

TEMPORARY: Delete/destroy incremental backup tapes when superseded by a full backup, or when no longer needed for system restoration, whichever is later.

Destroy/delete full backup tapes when second subsequent backup is verified as successful or when no longer needed for system restoration, whichever is later.

8. <u>Enterprise Administrative Support Environment (EASE).</u>

New Item

EASE Core was designed to function as an FDA-wide corporate repository that provides essential personnel, organization and locator data from 1985. EASE RAM was designed to provide current and historical reporting capability for administrative data such as trend analysis, statistical and adhoc reporting. It is used by employees to review their official personnel, location and timekeeping information. It also provides information on facilities and some training. Its data is fed to various FDA systems and linked to systems such as AIMS, Badge System, OFM Travel Manager, FACTS/OASIS and other modules. It superseded Administrative Resource Information Exchange System (ARIES). Data is protected under the Privacy Act and treated as a vital system.

- 8.1 <u>Inputs.</u>
- 8.1.1 Core and Other Data: Data prior to 1999 was migrated from ARIES.

 Personnel data created as temporary records for new employees within EASE is directly overwritten by the official information from Enterprise Human Resources and Payroll Project (EHRP) system operated by the Department. No input file is created for these. Also includes data on organization, locator, facilities and other areas entered by authorized users.

TEMPORARY: Destroy when no longer needed for verification of information. If input data is part of another records series, apply retention for that series.

Item No.	Records Description and Authorized Disposition	NARA Approved Citation
8.a.2	Employee Time and Attendance (ETA) Source Records	GRS 2, Item 7
	TEMPORARY: Destroy after GAO audit or when 6 years old whichever is sooner.	,
8.2	Data Files.	
8.2.1	Core and other data: Employee personnel, organization, location, facilities and other administrative data.	40
	TEMPORARY: When the official system has accepted the changes to the data files, the data is superseded and deleted.	
8.2.2	Employee Time and Attendance (ETA) InputRecords. (Note: this is also an input file as FDA sends this information to the Department's payroll system.)	GRS 2, Item 8
	TEMPORARY Destroy after GAO audit or when 6 years old whichever is sooner.	
8.3	Outputs.	
8.3.1	Reports generated by employees and offices.	
	TEMPORARY: All outputs are reference copies and can be destroyed when no longer needed. If a copy becomes part of another records series, apply retention for that series.	8
8.3.2	ETA: Reports generated by supervisors to document time and attendance for their offices and by individual employees for reference.	OF G
33	TEMPORARY: Delete when no longer needed for administrative or reference purposes.	×
8.4	System Documentation. Consists of database administration standard operating procedures (DBA SOP), System Manuals, User Manuals, File Format and Layouts, and Security Plans.	
	TEMPORARY : Destroy when superseded or obsolete, or when no longer needed for system operation.	

Item No. Records Description and Authorized Disposition

NARA Approved Citation GRS 24, Item 4

8.5 System Backup. Backup tapes maintained for potential system restoration in the event of a system failure or other unintentional loss of data.

TEMPORARY: Delete/destroy incremental backup tapes when superseded by a full backup, or when no longer needed for system restoration, whichever is later. Destroy/delete full backup tapes when second subsequent backup is verified as successful or when no longer needed for system restoration, whichever is later.

9. Administrative Resource Information Exchange System (ARIES). ARIES provided essential personnel, organization and locator information in the form of reports. Since 1999, the system has not been used except to extract historical data and access was limited to those in development and managerial roles in IT. All data has been migrated from ARIES to EASE in January 2004. It is protected under the Privacy Act.

TEMPORARY: Delete 2 years after final migration and verification of migration of information to EASE.

9.1 <u>Inputs.</u> There have been no inputs into this system since 1999.

TEMPORARY: Destroy when no longer needed for verification of information contained in the system.

9.2 <u>Data Files.</u> Data imported from various personnel, organization and locator systems.

TEMPORARY: Delete 2 years after final migration to EASE and verification of successful migration by quality control.

9.3 Outputs. Reports generated on an ad hoc basis for administrative and reference purposes.

TEMPORARY: Destroy when no longer needed.

9.4 <u>System Documentation.</u>

TEMPORARY: Destroy when superseded or obsolete, or after all data is successfully migrated into EASE and when no longer needed for administrative purposes, whichever is later.

New Item

Withdra WN April 12, 2005 ok by Seng Ja Sinatra æt meeting.

Item No. **Records Description and Authorized Disposition NARA Approved** Citation System Backup. Backups were made upon the receipt of each FDA 9.5 portion of the HHS personnel files. Operational data such as location data was updated as required. Production data was backed up daily by the National Institute of Health (NIH) computer center. **TEMPORARY.** Follow back up procedures documented by NIH. Destroy/delete when data in the system is completely migrated to EASE and no longer needed for administrative purposes. 10. Electronic Mail and Word Processing System Copies. Electronic copies of **New Item** records that are created on electronic mail and word processing systems and used solely to generate a recordkeeping copy of the records covered by the other items in this schedule. Also includes electronic copies of records created on electronic mail and word processing systems that are maintained for updating, revision, or dissemination. 10.1 Copies that have no further administrative value after the recordkeeping copy is made. Includes copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories on hard disk or network drives, and copies on shared network drives that are used only to produce the recordkeeping copy. **TEMPORARY:** Destroy within 180 days after the recordkeeping copy has been produced. 10.2 Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy.

TEMPORARY: Destroy when dissemination, revision, or updating is

completed.